Summary of safety and effectiveness of the new device:

FEB 0 5 2003

K030060

CERT Health Sciences, Inc.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SpineMED™

Name of Company:	CERT Health Sciences, LLC 11805B Coastal HWY, #9992 Ocean City, MD 21842-2460 Telephone: (866) 990-4444 Fax: (866) 990-4445
Contact Person:	Tim R. Emsky, Managing Partner CERT Health Sciences, LLC Telephone: (866) 990-4444 Fax: (866) 990-4445
Date of Summary Preparation:	December 4, 2002
Device Proprietary Name:	SpineMED™
Common Name:	Powered Traction Equipment
Classification Name:	Powered Traction Equipment
Class and Reference:	Class II (21 CFR Section 890.5900)
Product Code / Panel Code:	89ITH
Predicate Device	DRS System Professional Distribution Systems, Inc. 510(k): K981822

Device Description:

The SpineMED™ is a multi-function Hi-Lo traction Table designed to apply distraction forces to a patient's spine. The powered High–Low adjustments of the Table surface height are designed to provide easier loading and unloading of the patient on and off the table.

The patient lies in a supine position on the Table with the legs supported with a removable knee bolster. For increased comfort during distraction, and to provide relaxed distraction of paraspinal tissue, an infrared heating pad is incorporated into the table surface directly beneath the lumbar area. This 12 VDC infrared element can be turned on or off during treatment if a patient finds the heat uncomfortable.

The upper body is restrained through a chest harness, which is then attached to the fixed upper section of the Table, to a mechanical safety release buckle. The lower body is restrained to the moveable lower section of the Table through pelvic restraints that are designed to capture and secure the patient's iliac crest.

The SpineMED™ System consists of two main components: (1) The Table; and (2) The Control Console.

The control console provides the power and the computer control systems to drive the function of the unit, where the table is the functional component used for the treatment. Together, the components function as one unit.

The Table is a split-table design, whereby distraction tensions are applied to the patient through the pelvic restraints during the separation of the Table, resulting from the movement of the lower table section. The Pelvic Restraints are incorporated into a 10 inch section of the powered Lower Table section, which has a powered tilt function, that is designed to tilt the pelvis during treatment. This actuator driven tilting section has the ability to tilt the pelvis at a maximum of 25 degrees during treatment, to provide targeted treatment of specific spinal segments.

Intended Use

The SpineMED™ provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment session consists of a physician prescribed treatment period on the SpineMED™ and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain or sciatica. It relieves pain associated with herniated discs, bulging or protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Technological Characteristics

The SpineMED™ incorporates various principles and working characteristics of the predicate devices, the DRS System (K981822) and the SPINA System (K002260). The SpineMED™ employs a unique method of restraining the patient's body to the Table surface, which has not impacted on, or changed the safety or effectiveness of the device. Clinical trials carried out by the DRS System support the principles of decompression and the efficacy of this modality.

Summary of Safety and Effectiveness

The operating principles of the SpineMED™ Table permit the safe application of effective distraction tensions to the lumbar spine. The electrically operated energy source is constantly monitored and displayed by the internal computer. A Battery Backup System incorporated into the device, provides full operation of the device for 30 minutes in the event of a power failure, allowing for safe, uninterrupted treatment of the patient to the conclusion of the treatment session. The patient is provided with an electrical hand-held patient safety switch, which, when depressed, immediately interrupts the treatment session and gradually eliminates the application of force to zero under a controlled rate. This safety feature, in combination with the battery backup, minimizes the occurrence of muscle spasm, which can be caused by the sudden release of all tensions to zero, through a power failure or complete disengagement of the energy source. A secondary safety system, which incorporates a mechanically-operated release buckle for the upper harness, allows the patient to control its release by simply pulling a lever integrated into the side of the Table. Activating this release buckle results in the upper harness being disengaged from the Table, immediately eliminating all distraction forces to the patient.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 5 2003

Cert Health Sciences, LLC
c/o Heinz-Joerg Steneberg
Division Manager, Medical Division
TUV Rheinland of North America, Inc.
12 Commerce Road
Newtown, CT 06470

Re: K030060
Trade/Device Name: SpineMED™
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: January 21, 2003
Received: January 22, 2003

Dear Mr. Steneberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

for Mark N Milhem

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CERT Health Sciences, LLC

STATEMENT OF INDICATION FOR USE

510(k) Number: K030060

Device Name: **CERT Health Sciences, SpineMED™**

Indications for Use:

The SpineMED™ provides a program of treatments for relief from pain for those patients suffering with low back pain. Each treatment session consists of a physician prescribed treatment period on the SpineMED™ and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain or sciatica. It relieves pain associated with herniated discs, bulging or protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030060